Remarks

Claims 1-3 Are Not Unpatentable In View Of U.S. Patent No. 5,725,564

Applicants submit herewith a Terminal Disclaimer to overcome the nonstatutory obviousness-type double patenting rejection of claims 1-3 as being unpatentable over claims 7-25 of commonly owned U.S. Patent No. 5,725,564.

Claims 1 And 6 Are Not Unpatentable In View Of U.S. Patent No. 7,039,468

Applicants submit herewith a Terminal Disclaimer to overcome the nonstatutory obviousness-type double patenting rejection of claims 1 and 6 as being unpatentable over claims 1-11 of commonly owned U.S. Patent No. 7,039,468.

Claims 10-12, 14 And 15 Are Not Unpatentable Under 35 U.S.C. 103(a) Over A Combination Of U.S. Patent No. 4,895,154 Of Bartelt Et Al. And U.S. Patent No. 4,813,418 Of Harris

Claims 10-12, 14 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,895,154 of Bartelt et al. in view of U.S. Patent No. 4,813,418 of Harris.

The Bartelt patent describes a device for applying stimulating pulses "suitable for wound healing" through a plurality of electrodes. This device includes a pulse generator for generating a series of electrical pulses for application through pairs of electrodes, and a linear constant-current amplifier for each pair of electrodes that sets the intensity of the pulses at 30 mA, 35 mA or 40 mA. The pulse rate for this device is set at either 64 Hz or 128 Hz. The "typical" waveform that is generated by the Bartelt device, as illustrated in Figure 5, has an intensity of 35 mA and a current peak duration of 0.14 msec. The pulses are spaced approximately 7.8 msec

from each other at the 128 Hz pulse rate or 15.6 msec from each other at the 64 Hz rate. The output includes, in addition to the pulsed component, a galvanic DC component, the combination of which are considered to be effective to promote wound healing. (see col. 6, lines 17-28).

The Harris patent describes a method and apparatus for applying electrical stimulation to nerve fibers using a symmetrical biphasic waveform and multiple active electrodes. Symmetrical biphasic pulse pairs are utilized with each of the pulses of a pair being separated by an interval comparable to the refractory period for the particular nerve fibers being stimulated. As described at column 5, lines 3-55 (and as shown in Figure 4), a typical biphasic waveform produced by the Harris device for application for pain reduction comprises a total pulse duration within the range of about 1700 microseconds to about 2000 microseconds (with a total pulse duration of 1860 microseconds illustrated in Figure 4), including a first phase of about 50 microseconds to about 70 microseconds (with a first phase of 60 microseconds for channel A illustrated in Figure 4), an interphase interval of about 1630 microseconds to about 1950 microseconds (with an interphase interval of 1740 microseconds for channel A illustrated in Figure 4) and a second phase of about 50 microseconds to about 70 microseconds (with a second phase of 60 microseconds for channel A illustrated in Figure 4).

According to the Office Action, it would have been obvious at the time Applicants' invention was made to combine the biphasic waveform of the Harris patent with the pulse generator of Bartelt to produce Applicants' invention of claims 10-12, 14 and 15. However, the Bartelt device is useful for "wound healing" and the Harris device is useful for "pain reduction", as pointed out in the Office Action. Neither the Bartelt nor the Harris patents disclose, suggest or render

obvious an apparatus for generating a series of electrical pulses for application of neuromuscular electrical stimulation to a patient through a plurality of electrodes for treatment of oropharyngeal disorders, as required by Applicants' claims 10-12, 14 and 15. The application of neuromuscular electrical stimulation for treatment of oropharyngeal disorders is necessary to give meaning to these claims and to properly define the claimed invention. As described in Applicants' specification (at paragraph 0009 of Publication No. 2004/0220645 A1, which corresponds to page 4, lines 7-15 of the application as filed), neuromuscular electrical stimulation was not previously indicated for treatment of oropharyngeal disorders "because of concerns that the patient could develop spasms of the laryngeal muscles, resulting in closure of the airway or difficulty in breathing, and/or because of concerns that the introduction of electrical current into the neck near the carotid body would cause bradycardia and consequent hypotension." Nothing in the Bartelt or Harris patents discloses or suggests that neuromuscular electrical stimulation can be used for treatment of oropharyngeal disorders, as required by Applicants' claims 10-12, 14 and 15.

The Office Action states that "the circuitry of Bartelt [presumably as modified by Harris] is considered inherently capable of producing the waveforms with the recited parameters" of claims 11, 12, 14 and 15. However, at least with respect to claims 14 and 15, the Harris patent discloses biphasic pulses comprised of pulses of short duration separated by an interphase interval of relatively large duration, which pulses are not at all similar to the pulses described by Applicants' claims 14 and 15.

For the reasons set forth herein, Applicants request that this rejection of their claims 10-12, 14 and 15 be withdrawn, and that claims 10-12, 14 and 15 be allowed.

Claim 13 Is Not Unpatentable Under 35 U.S.C. 103(a) Over A Combination Of U.S. Patent No. 4,895,154 Of Bartelt Et Al., U.S. Patent No. 4,813,418 Of Harris, U.S. Patent No. 6,745,082 of Axelgaard And U.S. Patent No. 6,141,575 of Price

Claim 13 has been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,895,154 of Bartelt et al. in view of U.S. Patent No. 4,813,418 of Harris, U.S. Patent No. 6,745,082 of Axelgaard and U.S. Patent No. 6,141,575 of Price.

The Bartelt and Harris patents are described above. U.S. Patent No. 6,745,082 of Axelgaard describes a medical electrode which includes a two-piece snap connector assembly comprised of bottom eyelet 30 having a shaft 34 to which snap stud 32 is attached. A non-conductive flexible sheet 26 covers the top side of a flexible conductive member 12, and both these sheet components include a hole that is adapted to receive shaft 34 of bottom eyelet 30 so that the two sheet components 26 and 12 are sandwiched between eyelet 30 and snap stud 32. A layer of conductive hydrogel adhesive 36 is attached to the bottom of eyelet 30.

U.S. Patent No. 6,141,575 of Price describes a nonconductive band 11 having a plurality of rectangular cut-outs for electrodes that is intended to be placed on a patient's body in order to allow proper spacing and positioning of a plurality of electrodes for an electrocardiographic test. The nonconductive band may include a self-stick adhesive layer by which it may be affixed to the patient's chest; however, the cut-outs in the nonconductive band are sized to allow the

electrodes to "laterally slide for precise positioning purposes." (see column 3, lines 52-55). Once the proper locations for each of the electrodes are determined, backing 32 is removed from adhesive layer 31 of the electrode to allow the electrode to be attached to the skin of the patient. The nonconductive band of the Price assembly serves as a template for proper positioning of the electrodes. Since the nonconductive band allows the electrodes to slide laterally on the patient's skin, it does not secure the electrodes to the skin of the patient, as required by claim 13. Rather, the electrodes are secured to the patient's skin solely by their own adhesive backings. Even if the electrodes of the Axelgaard patent were substituted for those of the Price assembly, the nonconductive band of the Price assembly would not serve to secure the electrodes to the patient's skin, as required by claim 13. Rather, the nonconductive band of Price would serve as a template for locating the Axelgaard electrodes, which would then be attached to the patient's skin by the electrodes' hydrogel adhesive layers 36.

For the reasons described herein, Applicants submit that their invention, as defined by claim 13, is not disclosed, suggested or rendered obvious by a combination of the cited references. Applicants request therefore that this rejection of their claim 13 be withdrawn, and that claim 13 be allowed.

Claims 4, 5, 7 And 8 Are Allowable In View Of Filing Of Terminal Disclaimers

Objection has been raised to claims 4, 5, 7 and 8 as being dependent on a rejected base claim. All of these claims depend directly from claim 1, and both rejections of claim 1 have been obviated by the submission of Terminal Disclaimers. Applicants request, therefore, that the objection to claims 4, 5, 7 and 8 be withdrawn, and that claims 4, 5, 7 and 8 be allowed.

Applicants respectfully submit that all of their claims are patentable over the cited references. Applicants respectfully request, therefore, that the nonstatutory double patenting rejections of claims 1-3 and 6 be withdrawn, that the §103(a) rejections of claims 10-15 be withdrawn, the objections to claims 4, 5, 7 and 8 be withdrawn, and that claims 1-20 be allowed. If the Examiner has any questions about this Response, he is invited to call Applicants' attorney at the telephone number set out below.

Respectfully submitted,

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